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Cleanroom Construction: Materials Matter

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Reducing the cost of goods sold has become a focus of pharmaceutical facility, cleanroom, and process design, especially as blockbuster patents have begun to expire and generic competition has intensified. The need to minimize manufacturing costs sparked a multitude of creative ideas. Unfortunately, this creativity has resulted in almost as many concerns.

For example, eliminating redundant facilities or processes has resulted in single dedicated facilities, which can increase the risk of drug shortages.[1] Cleanroom ballroom designs with a lower cleanroom classification have been promoted, especially those utilizing single-use equipment processes. However, if designs are not well thought out, problems such as cross-contamination and batch rejections can result.

Taking a short-term view to reducing capital expenses may result in cutting corners on the quality of the facility construction materials. These shortcuts can cause major manufacturing disruptions and quality problems.

Cleanroom designs require thorough reflection on the intended purpose. In some cases, short-term solutions or lower-quality materials may be used when the process is expected to have a short life expectancy or the process environment does not pose critical risks. However, high-quality cleanrooms demand high-quality materials for wall and ceiling structures, doors, windows, electrical outlets, pipework, flooring, filters, duct work, etc.

Wall, flooring, and ceiling materials, for instance, are subjected to a multitude of activities. The quality of these materials is essential not only for cleanability, but also for durability and robust use. If surfaces cannot withstand frequent cleaning, they will deteriorate. Microfissures and cracks will appear in flooring or wall systems, providing microorganisms with the perfect breeding ground.

Frequent movement of people and equipment, accidentally dropping equipment parts, and

normal wear and tear can also cause cracks and diminish a material's plasticity. To compensate, one can apply epoxy coatings or other materials to help maintain plasticity. Wall, ceiling, and flooring surfaces can be treated with different polymeric coatings, provided these coatings do not experience outgassing and increase emission of volatile extractables. And mechanical instability is only one issue to keep in mind. Equally important are the plasticizer chosen and the chance of volatile release of antioxidants.

Other materials, like gypsum (drywall), one of the cheapest construction materials, are hygroscopic and adsorb moisture when the polymeric coating is damaged.[2] This can cause mold to proliferate within the wall or ceiling panels. To eliminate this contaminant, one has to remove all affected panels and perhaps adjacent ones, which may still be intact and in good shape. Construction with this material can disrupt processes and create problems in adjacent portions of the facility.[3]

Ceiling surfaces can vary between drywall, coated metal surfaces, and drop ceilings. Once again, the coated drywall should be robust enough to avoid any damage, which could result in particle shedding. Drop ceiling tiles should include gaskets to create a barrier to the space above. These tiles have the advantages of being lightweight making the space above the ceiling accessible. As with flooring and wall materials, the ceiling has to maintain its physical and chemical composition, even when treated with harsh sanitization agents.

Given the drug industry's intensifying focus on the cost of goods sold and its aversion to financial risk, savings now tops every manager's priority list. However, taking too short-term a view may result in selection of materials that won't hold up to the rigors of day-to-day use. Careful attention must be paid to material selection to ensure that the materials fit the cleanroom's intended use. Failing to do so can compromise product quality and, in the long run, corporate reputation.

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